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SMDA 510(k) SUMMARY

A. Submitter's Name, Address, Phone and Fax Numbers

Applicant:	Olympus Winter & Ibe, GmbH
Address:	Kuehnstr. 61 Hamburg 22045, Germany
Establishment Registration No.:	8010313
Submission Correspondent:	OLYMPUS AMERICA Inc.
Address:	Two Corporate Center Drive, Melville, NY 11747-9058

B. Name of Contact Person

Contact:	Laura Storms-Tyler
Title:	Director Regulatory Affairs
Telephone:	631-844-5688
Facsimile:	631-844-5554
Establishment Registration No.:	2429304
Initial Importer:	OLYMPUS AMERICA Inc.
Address:	Two Corporate Center Drive, Melville, NY 11747-9058
Establishment Registration No.:	2429304

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Single use balloon dilator MaxPass™
Common Name:	Balloon dilation catheter
Classification:	Biliary catheter and accessories 21 CFR 876.5010
Predicate Device:	Microvasive Rapid Exchange™ Biliary Balloon Dilation Catheter (K001338 Boston Scientific Corporation) Bard biliary Balloon Dilators (K920361 C.R.Bard, Inc.)

D. Description of the Device(s)

Single use balloon dilator Maxpass ™ is a triple lumen catheter with a balloon mounted at the distal end of the catheter. Balloon dilators are used to exert radial force to dilate narrow duct segments, as well as the Sphincter of Oddi.

E. Intended Use of the Device(s)

Single use balloon dilator Maxpass ™ to be used in conjunction with Olympus endoscopes for dilating strictures of the biliary tree and the major papilla during endoscopic applications.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the Single use balloon dilator Maxpass ™ does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2005

Ms. Laura Storms-Tyler
Executive Director
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K050502
Trade/Device Name: Single use balloon dilator MaxPass™
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 5, 2005
Received: July 6, 2005

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050502

Indications for Use

510(k) Number (if known): ~~None~~ K050502

Device Name: Single use balloon dilator MaxPass™

Indications For Use: Single use balloon dilator Maxpass ™ to be used in conjunction with Olympus endoscopes for dilating strictures of the biliary tree and the major papilla during endoscopic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050502